INTERVIEW SUMMARY

Applicant's Representative thanks Examiner Padmashri Ponnaluri for the opportunity to interview this application by telephone on August 12, 2003. Issues relating to rejections of the claims under 35 U.S.C. § 112 and 35 U.S.C. § 102(e) were discussed during the interview, as were proposed amendments to the claims. Applicant has amended the claims in accordance with the Examiner's suggestions.

REMARKS

Applicant has carefully reviewed and considered the Office Action mailed on March 21, 2003, and the references cited therewith.

Claims 27-29 are pending. Claims 27-29 are amended. The subject matter of claim 27 has been amended to include a description of the fibronectin type III (Fn3) polypeptide monobodies in the fibronectin-peptide display library. This description for the Fn3 polypeptide monobodies is present in the claims of a related, allowed case, U.S. Application Ser. No. 09/096749. A copy of the allowed claims from U.S. Application Ser. No. 09/096749 is attached. Support for this description of the Fn3 polypeptide monobodies can be found in original claim 1 and throughout the specification, for example, at Page 6, Line 24 to Page 7, Line 20 and in the Examples. Claims 28-29 have been amended to refer to the fibronectin-peptide display library of claim 27. Applicant submits that no new matter has been added by such amendments and that the amendment of claims 27-29 does not limit the scope of equivalents to which any claim element is entitled.

During the interview on August 12, 2003, the Examiner mentioned that Applicant may not be entitled to product-by-process claims. Applicant submits that the present claims are not product-by-process claims. Moreover, even if the Patent Office holds that process steps for producing the libraries of the invention are not considered when determining patentability, the presently claimed libraries are novel and patentable in and of themselves. In particular, as defined by the claims of the invention, each fibronectin-peptide display library of the invention comprises a Fn3 polypeptide monobody, wherein at least one monobody loop region sequence varies as compared to the wild-type (SEQ ID NO:110, Figure 2) loop region sequence by

deletion, insertion or replacement certain amino acids. Hence, the present libraries are structurally distinct from previously available libraries. Moreover, Applicant was the first to recognize that such changes in monobody loop region sequences could generate useful fibronectin-peptide display libraries that are capable of binding a specific binding partner (SBP) and thereby acting like smaller, improved versions of antibody preparations, e.g. like polyclonal antibody preparations.

Corrected Filing Receipt

Applicant has received a corrected filing receipt that correctly reflects the applications from which Applicant claims priority. The Examiner has indicated that the request for the corrected filing receipt makes reference to foreign priority applications. Such reference to earlier filed foreign applications was a grammatical error. Applicant regrets any confusion caused by this error.

Substitute Specification

The Examiner has noted that a substitute specification was submitted on December 19, 2001 but has stated that the substitute specification has not been entered because a statement as to lack of new matter under 37 C.F.R. § 1.125(b) was allegedly not made. Applicant submits that a statement was made that the substitute specification contains no new matter in the Response to Second Restriction Requirement filed with the substitute specification on December 19, 2001, a copy of which is attached. Accordingly, Applicant respectfully requests entry of the substitute specification.

Drawings

The Examiner has noted that informal drawings were filed with the specification and has requested that formal drawings be submitted when the application is allowed. Formal drawings are enclosed herewith (Figs. 1A through 17C – 19 sheets).

Claim 27 Informality

The Examiner has objected to claim 27 as depending from claim 15, which has been withdrawn from this case. Applicant has amended claim 27 as described above. Accordingly, Applicant submits that this objection is obviated.

§112, Second Paragraph Rejection of the Claims

Claims 27-29 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite because claim 27 recites "derived from the variegated nucleic acid library of claim 15." Claim 27 has been amended as described above and no longer contains this phrase. Applicant submits that the rejection under 35 U.S.C. § 112, second paragraph, as it relates to claim 27 should be withdrawn.

Claims 27-29 were rejected under 35 U.S.C. § 112, second paragraph, as indefinite because no antecedent basis allegedly exists in claim 28 for "the peptide." Antecedent support now exists in Claim 27 for a peptide. Hence no further amendment of Claim 28 is needed and Applicant respectfully requests that this rejection under 35 U.S.C. § 112, second paragraph, as it relates to claim 28 be withdrawn.

§112, First Paragraph Rejection of the Claims

Claims 27-29 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description for a peptide display library. The Examiner has asserted that "a precise definition, such as by structure, formula [or] chemical name" is required.

Claim 27 is directed to a fibronectin-peptide display library comprising fibronectin type III (Fn3) polypeptide monobodies, each Fn3 polypeptide monobody comprising at least two Fn3 β-strand domain sequences with a loop region sequence linked between each Fn3 β-strand domain sequence, wherein at least one monobody loop region sequence varies as compared to the wild-type (SEQ ID NO:110, Figure 2) loop region sequence by deletion of two to twelve amino acids in the loop region sequence, insertion of at least two to 25 amino acids, or replacement of at least two amino acids in the loop region sequence, and wherein the polypeptide monobody loop region comprises a peptide with at least two amino acids that binds to a specific binding partner (SBP) to form a polypeptide:SBP complex.

Applicant submits that the specification provides a written description of each and every element of Claims 27-29 that would reasonably convey to one of skill in the art that the inventors were in possession of the claimed invention at the time of filing. However, in order to expedite the prosecution of this application the claims have been amended to refer to the wild-type Fn3 (SEQ ID NO:110, Figure 2) loop region. Applicant requests withdrawal of this rejection under 35 U.S.C. § 112, first paragraph.

§102 Rejection of the Claims

Claims 27-29 were rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent 6,348,584 B1 to Hodgson et al. The Examiner has alleged that Hodgson et al. discloses fibronectin binding protein compounds and DNA encoding fibronectin binding proteins.

Claim 27 is directed to a fibronectin-peptide display library comprising fibronectin type III (Fn3) polypeptide monobodies, each Fn3 polypeptide monobody comprising at least two Fn3 β-strand domain sequences with a loop region sequence linked between each Fn3 β-strand domain sequence, wherein at least one monobody loop region sequence varies as compared to the wild-type (SEQ ID NO:110, Figure 2) loop region sequence by deletion of two to twelve amino acids in the loop region sequence, insertion of at least two to 25 amino acids, or replacement of at least two amino acids in the loop region sequence, and wherein the polypeptide monobody loop region comprises a peptide with at least two amino acids that binds to a specific binding partner (SBP) to form a polypeptide:SBP complex.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). To constitute anticipation, the claimed subject matter must be identically disclosed in the prior art. *In re Arkley*, 172 U.S.P.Q. 524 at 526 (C.C.P.A. 1972). For anticipation, there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the art. *Scripps Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565, 18 U.S.P.Q.2d 101 (Fed. Cir. 1991). To overcome the defense of anticipation, "it is only necessary for the

patentee to show some tangible difference between the invention and the prior art." *Del Mar Engineering Lab v. Physio-Tronics, Inc.*, 642 F.2d 1167, 1172, (9th Cir. 1981).

Applicant submits that U.S. Patent 6,348,584 B1 to Hodgson et al. is limited to a disclosure of molecules that bind to fibronectin molecules and provides no disclosure whatsoever of a library of fibronectin type III molecules or any teachings on how to modify the fibronectin type III molecule to bind other molecules. For example, the first paragraph of the Description of the Invention at col. 6, line 60 to col. 7, line 4, clearly states that U.S. Patent 6,348,584 relates to proteins that bind fibronectin:

> The invention relates to Fibronectin Binding Protein polypeptides and polynucleotides as described in greater detail below. In particular, the invention relates to polypeptides and polynucleotides of a Fibronectin Binding Protein of Staphylococcus aureus, which is related by amino acid sequence homology to S. aureus fibronectin binding protein A polypeptide. The invention relates especially to Fibronectin Binding Protein having the nucleotide and amino acid sequences set out in Table 1 [SEQ ID NO: 1] and Table 1 [SEQ ID NO: 2] respectively, and to the Fibronectin Binding Protein nucleotide sequences of the DNA in the deposited strain and amino sequences encoded thereby.

The sequences shown in Table 1 of U.S. Patent 6,348,584 are clearly distinct from fibronectin sequences (*see, e.g.*, SEQ ID NO:110, Figure 2 of the present application). Accordingly, the claims of the present application are distinct from those of U.S. Patent 6,348,584 and this rejection under 35 USC § 102(e) should be withdrawn.

Given that the fibronectin-peptide display libraries are structurally and functionally distinct from the prior art, including U.S. Patent 6,348,584 B1 to Hodgson et al., Applicant submits that the claimed invention is not anticipated and respectfully requests withdrawal of this rejection under 35 U.S.C. § 102(e).

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612-373-6961) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 20 day of August, 2003.

Candis B. Buending

Name Signature